

**RULES
OF
DEPARTMENT OF COMMUNITY HEALTH**

Please Note: The Department of Community Health provides this electronic version of the Administrative Rules and Regulations as a service to the public. Though every effort is made to insure the accuracy of this material, certain errors or omissions may exist within these documents. The electronic version of the rules may not be substituted for the official, published version of the Rules and Regulations and should not be used as the sole basis to initiate any proceeding or action. The official compilation of Administrative Rules and Regulations is published by the Office of Secretary of State, pursuant to O.C.G.A. 50-13-7; the printed compilations are available in public libraries and state agencies and the official electronic version is located on the Secretary of State's website at the following address:

http://rules.sos.state.ga.us/pages/DEPARTMENT_OF_COMMUNITY_HEALTH/index.html.

**111-2
HEALTH PLANNING**

**111-2-2
Certificate of Need**

111-2-2-.41 Specific Review Considerations for Positron Emission Tomography Units.

(1) **Applicability.** A certificate of need will be required for a new or expanded positron emission tomography (PET) unit.

(2) **Definitions.**

(a) "Health Planning Area" or "planning area" means the 13 geographic regions in Georgia as defined in the official State Health Component Plan for use in planning for PET Scan services.

(b) "Horizon Year" means the last year of a five-year projection period for need determinations.

(c) "Expansion" or "expanded service" means the addition of a fixed unit to an existing service or, in the case of a mobile unit, the addition of a new site not previously served by such mobile unit. The addition of a component or components, such as computer tomography (CT) imaging, to an existing fixed or mobile unit or the upgrade of an existing fixed or mobile unit shall not be considered an expansion and shall not be subject to the need standards; provided, however, that if any such addition or upgrade is subject to review due to the equipment threshold at that time, the applicant shall demonstrate compliance with or document a plan and agreement to comply with 111-2-2-.41(3)(d), (e), (f), and (g).

(d) "Fixed Unit" means a unit that is stationary within one approved facility.

(e) "Mobile Unit" means a unit that is shared by two or more health care facilities and which has a data acquisition system and a computer. In order to meet the definition of mobile unit, the applicant must provide proof of the following:

1. The unit must be on site at each Facility identified in the application at least three (3) days per month.
2. The unit must not be on site at any Facility more than three (3) consecutive operating days per week or twelve (12) total days per month.
3. The facilities involved with the mobile unit are fully informed and participating in the service as evidenced by written agreements or correspondence provided in the application.
4. The applicant, if successful, is limited to providing service only for those facilities approved in the application. Additional facilities may be added to the service list only through an approved application for expansion. The applicant, if successful, may eliminate sites approved in the application; provided that all standards and criteria will still be met and the mobile unit provider and the site being eliminated jointly notify the department in writing of their intent to eliminate the site.
5. The applicant shall project scans per facility on a pro-rated basis for the first year of operation, and such projections shall be used in any need determinations during that first year of operation. Thereafter, in annual surveys, the applicant, if successful, must document scans by each service facility for use in need determinations.

(f) "Optimal Utilization" refers to scans per year and shall be defined as 1,500 PET scans per year regardless of whether the diagnostic equipment is a standalone PET scanner or includes another component such as CT. A PET Scan or Study means the gathering of data during a single patient visit from which one or more images may be constructed.

(g) "PET Scan Service" or "Service" means a facility that owns one or more units and provides diagnostic imaging through positron emission tomography exclusively or as a dedicated PET/CT unit.

(h) "Positron Emission Tomography" or "PET" means a noninvasive diagnostic technology, which enables the body's physiological and biological processes to be observed through the use of positron emitting radiopharmaceuticals.

(i) "Unit" means a single piece of equipment that performs PET scans.

(3) Standards.

(a) The need for a new or expanded service shall be determined through the application of a Numerical Need method and an assessment of the aggregate utilization rate of existing and approved units.

1. The numerical need for a new unit in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps listed below, and all data elements relate to each planning area:
 - (i) Calculate the projected incidence of cancer for each county by multiplying the most recent Cancer Incidence Rate, as published by the State Cancer Registry, for each county by the horizon year population for the county;
 - (ii) Multiply the projected incidence of cancer by 50% to determine the projected number of patients diagnosed with cancer who might benefit from a scan.
 - (iii) Add the number of cancer cases that might benefit from a scan for each county within a Health Planning Area to determine the estimated need for services within a Health Planning Area for persons diagnosed with cancer.
 - (iv) Multiply the number of cancer cases for each Health Planning Area from subsection (iii) by 1.5 to accommodate for non-oncology patients and for follow-up scans for oncology patients in the projected need for services.
 - (v) Calculate the number of needed units by dividing the number of individuals who might receive scanning services as determined from subsection (iv) by 1,500, which represents the optimal utilization of a unit. Following the determination of whole numbers representing units, if the balance net numerical need in any Health Planning Area is at or above 75% of a unit (1125 individuals needing scans), the needed units shall be rounded up by one unit.
 - (vi) Determine the net numerical unmet need for PET scan unit(s) by subtracting the total number of units currently existing or approved for use from the number of needed units.
2. Prior to the approval of a new or expanded unit in a planning area, the aggregate utilization rate for all existing and approved units in that planning area shall equal or exceed 90% of optimal utilization for the most recent survey year.
 - (b)
 1. An applicant seeking an expansion or expanded service for a fixed unit may be approved only if all provisions of the need standards in 111-2-2-.41(3)(a) and all other standards in the Rules are met.
 2. An applicant seeking an expansion or expanded service for a mobile unit may be approved, without meeting the need standards of 111-2-2-.41(3)(a)1.; provided that the planning area in which the applicant is seeking the expansion or expanded service shows a net numerical unmet need of more than 25% of a unit (375 individuals needing scans) but less than 75% of a unit (1125 individuals needing scans) and provided that all other standards are met and that the affiliation, transfer, or referral agreements provided pursuant to 111-2-2-.41(3)(f)1. are executed with a hospital or hospitals within the planning area in which the mobile unit seeks to expand.

(c) Exceptions to the need standards and requirements in (c)(1) may be granted by the Department for an applicant seeking to remedy an atypical barrier to services based on cost, quality, financial access, or geographic accessibility.

(d) 1. In considering applications joined for review, the Department may give favorable consideration to an applicant seeking approval for a service with a unit that includes both PET and CT scan capabilities.

2. In considering applications joined for review, the Department may give favorable consideration to an applicant that has historically provided a higher annual percentage of un-reimbursed services to indigent and charity patients.

(e) An applicant for a new or expanded service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant that stipulates that any such services shall be provided regardless of race, age, sex, creed, religion, disability, or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy; and

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds five (5) percent of annual, adjusted gross revenues of the PET scan service or, in the case of an applicant providing other health services, the applicant may request that the Department allow the commitment for services to indigent and charity patients to be applied to the entire facility;

3. providing a written commitment to participate in Medicaid, Peach Care and Medicare programs, to the extent such programs reimburse for PET scan services, and to accept any Medicaid-, Peach Care- and/or Medicare-eligible patient for services;

4. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(f) An applicant for a new or expanded service shall provide evidence of the ability to meet the following quality of care standards:

1. Document certification or a plan for securing certification for operation of a unit from the Georgia Department of Natural Resources.

2. Document that the unit proposed for purchase is approved for use by the U.S. Food and Drug Administration and for reimbursement by the Center for Medicare and Medicaid Services.
 3. Document that the service will function as a component of a comprehensive diagnostic service and that appropriate referral to treatment and follow-up will be provided. The applicant must have accessible the following modalities and capabilities on site or through contractual agreements, as evidenced by documentation provided at the time of application: computed tomography, magnetic resonance imaging, nuclear medicine, and conventional radiography.
 4. Document that the PET service shall be under the direction of a physician who is board certified in nuclear medicine or diagnostic radiology or has successfully completed a 6-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience; and is licensed as an authorized user of radioactive materials in accordance with the Rules of the Georgia Department of Natural Resources.
 5. Document the training and experience in PET scan services of the physician, nuclear medicine technologist, radiology technologist, and operational personnel.
 6. Document fully the safe and timely access to radiopharmaceuticals.
- (g) An applicant for a new or expanded service shall provide evidence of the ability to meet the following continuity of care standards:
1. Document that the applicant provides, or has signed affiliation, transfer, or referral agreements with one or more hospital(s) and health care organizations that provide the following: comprehensive cancer services, including radiation oncology, medical oncology, and surgical oncology; open heart surgery; medical education; and services for persons with Alzheimer's or other dementias.
 2. Document a referral system that includes a feedback mechanism for communicating scan results and any other pertinent patient information to the referring physician.
 3. Document that the applicant will maintain current listings of appropriate clinical indications for PET procedures and will provide such listings to referring physicians and patients.
 4. Document how medical emergencies will be managed in conformity with accepted medical practice.
- (h) An applicant for a new or expanded service shall agree to provide the department with all requested information and statistical data related to the operation and provision of services and to report that data to the department in the time and format requested by the department.